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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,233	04/26/2000	PHILIPPE SEGUELA	PCI-017USRCE2	3952
959	7590	12/15/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			PAK, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 12/15/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/530,233	SEQUELA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-21,38 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-21,41 and 43 is/are allowed.
- 6) ☒ Claim(s) 38, 40, 42, 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Amendment***

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 26, 2006 has been entered.

2. Amendment filed September 26, 2006 has been entered. Claims 16-21, 38, 40-44 are pending. Claims 1-15, 23-37 and 39 are cancelled.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicant's arguments filed September 26, 2006 have been fully considered but they are not found persuasive.

***Claim Rejections - 35 USC § 112***

Art Unit: 1646

5. Claims 38, 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims recite or encompass the term "85% identical" which is ambiguous and the metes and bounds of the term is not clear. The term "% identical" is a relative term whose metes and bounds are not clear because one skilled in the art requires specific algorithms in order to calculate % identity. Applicants argue that the % identity alignment provided by the examiner is incorrect because the applicants' alignment gives different results. Thus, the metes and bounds of the term % identity is ambiguous without the specific algorithm recitation in the claims. Furthermore, it is not clear to one skilled in the art when an "85% identical" polypeptide is human or when it is not human or any other species unless it is the specific human species of SEQ ID NO:2 disclosed in the specification.

Applicants argue that calculation is percent identity and not percent similarity. However, previously attached sequence comparison provide sequence identity. Definitions are relative and percent identity require specific algorithm to complete the calculation.

6. Claims 38, 40, 42 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

Art Unit: 1646

the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims 38, 40, and 42 encompass or recite "85% identical" which encompass variants of SEQ ID NO:2. Claim 44 recite or encompass "nucleic acid molecules which hybridizes" which encompasses a large genus of variants of SEQ ID NO:2. However, one skilled in the art cannot envision all the various species of peptide which has "85% identity with SEQ ID NO:2 with the function of being inhibited by amelioride".

Furthermore, one skilled in the art cannot envision all the various species of peptides which is encoded by a "nucleic acid molecules which hybridizes" to SEQ ID NO:1 and without a defined function. Hybridization occurs between most complex nucleic acid molecules because there are regions which align between the nucleotide sequence. Hybridization is defined by  $Cot_{1/2}$  which is combination of concentration and time where the 50% interaction is found between nucleic acid molecules. Thus at any given time, nucleic acids are at 50% hybridization according to  $Cot_{1/2}$  calculation. Furthermore, without washing condition there are always non-specific hybridization which is different from the  $Cot_{1/2}$  calculation and thus binds non-specifically to other molecules. The specification discloses the specific species of SEQ ID NO:2 and the claims encompass a large number of species which cannot be envisioned and whose function is not specifically defined. While the species of SEQ ID NO:2 is human and functions to inhibit amelioride, one skilled in the art cannot envision the difference in structure from SEQ ID NO:2 which provides the characteristic of being human. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or

Art Unit: 1646

mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of polynucleotide structure cannot be envisioned.

Applicants argue that written description does not require that each and every embodiment encompassed by the claim be disclosed. However, the USPTO written description guideline and *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Situation in the present claims are similar to the guidelines provided.

### ***Priority***

7. Applicant's claim for priority under 35 U.S.C. 119(a-d) is acknowledged. However, the foreign application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 38, 40 and 42 of this application for the reasons provided above in the 35 USC 112 rejections. See MPEP 706.02.

### ***Claim Rejections - 35 USC § 102***

8. Claims 38, 40, 42 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by DeWeille et al. (US 6,287,859).

DeWeille et al. disclose the proton gated cation channel from sensory neurons (SEQ ID NO: 14) which has 99.4% amino acid sequence identity with SEQ ID NO: 2. The channels of DeWeille et al. inherently have the P2X2 ATP channel activity as well

Art Unit: 1646

as the functional activity including amelioride inhibition. The channels of DeWeille et al. inherently belong to the degenerin family.

Applicants argue that presently claimed subject matter has priority date earlier than the earliest priority date of February 11, 1998 of DeWeille et al. However, the priority has been denied as discussed above.

Claim 44 recite hybridization limitations which is met by DeWeille et al. because hybridization occurs between most complex nucleic acid molecules because there are regions which align between the nucleotide sequence especially nucleic acids which encodes proteins which share 99.4 % amino acid sequence identity. Hybridization is defined by  $Cot_{1/2}$  which is combination of concentration and time where the 50% interaction is found between nucleic acid molecules. Thus at any given time, nucleic acids are at 50% hybridization according to  $Cot_{1/2}$  calculation. Furthermore, without washing condition there are always non-specific hybridization which is different from the  $Cot_{1/2}$  calculation and thus binds non-specifically to other molecules.

9. Claims 38, 40, 42 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Renard et al. (US 2002/0173000).

Renard et al. disclose the proton gated cation channel from sensory neurons (SEQ ID NO: 6) which has 94.9% amino acid sequence identity with SEQ ID NO: 2. The channels of Renard et al. inherently have the P2X2 ATP channel activity as well as the functional activity including amelioride inhibition. The channels of Renard et al. inherently belong to the degenerin family.

Art Unit: 1646

Applicants argue that presently claimed subject matter has priority date earlier than the earliest priority date of May 15, 1998 of Renard et al. However, the priority has been denied as discussed above.

Claim 44 recite hybridization limitations which is met by DeWeille et al. because hybridization occurs between most complex nucleic acid molecules because there are regions which align between the nucleotide sequence especially nucleic acids which encodes proteins which share 99.4 % amino acid sequence identity. Hybridization is defined by  $Cot1/2$  which is combination of concentration and time where the 50% interaction is found between nucleic acid molecules. Thus at any given time, nucleic acids are at 50% hybridization according to  $Cot1/2$  calculation. Furthermore, without washing condition there are always non-specific hybridization which is different from the  $Cot1/2$  calculation and thus binds non-specifically to other molecules.

10. Claims 16-21, 41 and 43 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.



Art Unit: 1646

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Michael D. Pak". The signature is written in a cursive, slightly slanted style.

Michael Pak  
Primary Examiner  
Art Unit 1646  
December 11, 2006